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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,737	07/09/2001	Edouard G. Lebel	S-21043B	1621

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,737	LEBEL ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004 and 12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,12-23 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,12-23 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/11/01* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 March 2004 has been entered.

2. Claims 6-9, 12-23 and 30 are pending.

3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948, which states that the lines, letters and numbers in Figure 1 are of uneven quality. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejections of claims 6-9, 12-13, 18-23 and 30 under 35 U.S.C. 102(e) as being anticipated by Ryals et al (US Patent 5,614,395, filed January 1993), claims 6-7 and 17-23 under 35 U.S.C. 102(b) as being anticipated by Yoshikawa et al (1993, Naturwissenschaften 80:417-420) in light of each of Takeuchi et al (1990, Plant Physiol. 93:673-682) and Melchers et al (1993, Plant Mol. Biol. 21:583-593), claims 6-7, 12-13, 18 and 21 under 35 U.S.C. 102(e) as being anticipated by Borriss et al (US Patent 5,470,725, filed February 1990) and claims 6-7, 11-15 and 17-23 under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al in view of Lao

et al (1991, J. Bacteriol. 173:3397-3407) are withdrawn in light of Applicant's arguments filed 25 September 2003.

Claim Objections

6. Claim 13 is objected to because "derives" should be --is derived--.

Claim Rejections - 35 USC § 112

7. Claims 6-9, 12-23 and 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 6, 12-13 and 21 are indefinite in their recitation of "cellulase". The specification on pg 3, lines 14-25, states that cellulase enzyme systems are made up of β-1,4-endoglucanases (EC 3.2.1.4), β-1,4-exoglucanases (EC 3.2.1.91), and 1,4-β-D-glucosidases (EC 3.2.1.21). The enzyme nomenclature database maintained by Swissprot (http://kr.expasy.org/enzyme, 2004) defines a cellulase only as β-1,4-endoglucanases (EC 3.2.1.4) (http://kr.expasy.org/cgi-bin/enzyme-search-de, 2004). In arguments filed 12 April 2004 Applicant quotes Lashbrook et al to state that endo-β-1,4-glucanase (EC 3.2.1.4) is not a cellulase. Thus, it is quite unclear what enzymes Applicant intends to be encompassed by the term "cellulase".

8. Claims 6-9, 12-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 25 March 2003, as applied to claims 6-9, 12-14, 16-23 and 30. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of plants transformed with DNA molecules that encode any cellulase from any source.

Thomas et al teaches that more than 60 species of fungi and 46 species of bacteria produce cellulases (pg 210, paragraph 2). The specification, via Thomas et al, Collmer et al, Ghangas et al, Wilson, and Lao et al, teaches a total of about 20 endoglucanase (presumably β-1,4-endoglucanse) coding sequences from about 12 bacterial species and one fungal species, 2 cellobiohydrolase coding sequences, one from a bacterial species and one from a fungal species, and 2 β-glucosidase coding sequences, one from a bacterial species and one from a fungal species. A single fungal and a single bacterial cellobiohydrolase coding sequence do not describe a representative number of all fungal and bacterial cellobiohydrolase coding sequences. A single fungal and a single bacterial β-glucosidase coding sequence do not describe a representative number of all fungal and bacterial β-glucosidase coding sequences. A single fungal β-1,4-endoglucanse coding sequence does not describe a representative number of all fungal β-1,4-endoglucanse coding sequences.

Claim 14 is drawn a plant transformed with a cellulase from any *Thermomonospora* species; however, the specification describes only β-1,4-endoglucanses from one species, *T. fusca*. However, the *Thermomonospora* genus includes 6 other species, *T.alba, T. chromogena,*

T. curvata, T. formosensis, T. mesophila, and *T. mesouviformis*; no nucleic acids encoding cellulases are described from any of these species.

Claim 15 is drawn a plant transformed with a cellulase from *T. fusca*. The only cellulase-encoding nucleic acids from *T. fusca* described in the specification all encode β-1,4-endoglucanses; no β-glucosidase or cellobiohydrolase coding sequences from *T. fusca* are described.

The specification also does not describe any cellulase coding sequence from plants.

Hence, Applicant has not described plants transformed with DNA molecules that encode cellulases within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that the written description needs to be specific enough to lead the skilled artisan to the class of DNA molecules that encode cellulases and does not need to describe all cellulases (response pg 2-3).

This is not found persuasive because the specification must describe a representative number of cellulase coding sequences within the full scope of the claims, and it does not.

Applicant urges that the specification teaches *T. fusca* E1, E2, E4 and E5 genes, that Collmer et al teaches references that teach two other cellulase genes, that Yoo et al teaches a endoglucanase and a β-glucosidase, and that Thomas et al teaches a number of cellulases

(response pg 3-4).

This is not found persuasive because, as detailed above, these references do not teach a representative number of bacterial and fungal β-1,4-endoglucanses, β-glucosidase or cellobiohydrolase coding sequences.

Applicant urges that the examples describe plants transformed with *T. fusca* E1and E5 genes, which encode β-1,4-endoglucanses, and with the *T. fusca* E2 gene, which encodes a cellobiohydrolase (response pg 4).

This is not found persuasive. The *T. fusca* E2 gene, referenced as GenBank Accession No. M73321 in the specification (pg 14, line 25) is a β-1,4-endoglucanse (see GenBank Accession No. M73321, 1998. See also Lao et al, pg 3397, left column, paragraph 2). Thus, the examples describe no plants transformed with nucleic acids encoding β-glucosidases or cellobiohydrolases and no plants transformed with β-1,4-endoglucanses from organisms other than *T. fusca*.

9. Claims 6-9, 12-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *T. fusca* β-1,4-endoglucanse-encoding sequences and plants transformed with them, does not reasonably provide enablement for nucleic acids encoding all cellulases, plants transformed with those cellulases, or non-transformed plants that express cellulases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 25 March 2003, as applied to claims 6-9, 12-14, 16-23 and 30. Applicant's

arguments filed 12 April 2004 have been fully considered but they are not persuasive.

The claims are broadly drawn to plants transformed with a nucleic acid encoding any cellulase from any source.

In contrast, the instant specification, however, only provides guidance for expression of constructs comprising a nucleic acid encoding the *T. fusca* E1, E2 or E5 β-1.4-endoglucanse operably linked to the tobacco PR-1a or the CaMV 35S promoter in tobacco, maize or wheat (example A) and similar expression in plants of constructs encoding fusion proteins of those endoglucanases and a vacuolar signal sequence (example B). The specification, via Thomas et al, Collmer et al, Ghangas et al, Wilson, and Lao et al, teaches a total of about 20 endoglucanase (presumably β-1,4-endoglucanse) coding sequences from about 12 bacterial species and one fungal species, 2 cellobiohydrolase coding sequences, one from a bacterial species and one from a fungal species, and 2 β-glucosidase coding sequences, one from a bacterial species and one from a fungal species.

The instant specification fails to provide guidance for a representative number of other nucleic acids encoding cellulases, and hence for all plants comprising said nucleic acids.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that the specification teaches *T. fusca* E1, E2, E4 and E5 genes, that Collmer et al teaches references that teach two other cellulase genes, that Yoo et al teaches a endoglucanase and a β-glucosidase, and that Thomas et al teaches a number of cellulases (response pg 5).

This is not found persuasive. Thomas et al teaches that more than 60 species of fungi and 46 species of bacteria produce cellulases (pg 210, paragraph 2). However, the specification only teaches a single fungal cellobiohydrolase coding sequence, a single fungal β-glucosidase coding sequence, and a single fungal β-1,4-endoglucanse coding sequence. A representative number of fungal cellulase coding sequences are not taught. The specification only teaches a single bacterial cellobiohydrolase coding sequence, a single bacterial β-glucosidase coding sequence, and only about 20 bacterial β-glucosidase coding sequences. A representative number of bacterial cellulase coding sequences are not taught.

Claim 14 is drawn a plant transformed with a cellulase from any *Thermomonospora* species; however, the specification teaches only β-1,4-endoglucanses from one species, *T. fusca*. However, the *Thermomonospora* genus includes 6 other species, *T.alba, T. chromogena, T. curvata, T. formosensis, T. mesophila,* and *T. mesouviformis*; no nucleic acids encoding cellulases are taught from any of these species.

Claim 15 is drawn a plant transformed with a cellulase from *T. fusca*. The only cellulase-encoding nucleic acids from *T. fusca* taught in the specification all encode β-1,4-endoglucanses; no β-glucosidase or cellobiohydrolase coding sequences from *T. fusca* are taught.

The specification also does not teach any cellulase coding sequence from plants.

Applicant urges that the specification describes that cellulases include endocellulases, exocellulases and celliobioses and that these have been cloned and may be used in the invention (response pg 5).

This is not found persuasive because the specification does not teach a representative

number of nucleic acids encoding cellulases, and hence a representative number of plants comprising said nucleic acids.

Applicant urges that the specification provides guidance for optimization of microbial sequences for expression in plants, and plant transformation vectors and methods (response pg 6).

This is not found persuasive because the rejection is not drawn to this aspect of the invention.

Applicant urges that there are working examples of plants transformed with *T. fusca* E1, E2 and E5 coding sequences fused to inducible or constitutive promoters, in monocots and dicots, and with various targeting signals; these working examples provide sufficient guidance and direction to one of skill in the art to do routine experimentation (response pg 6-7).

This is not found persuasive because the specification insufficiently teaches cellulase coding sequences, in comparison to the scope of the claims.

Claim Rejections - 35 USC § 103

10. Claims 6-8, 16-19 and 21-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (1992, US Patent 5,168,064). The rejection is repeated for the reasons of record as set forth in the Office action mailed 25 March 2003. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

The claims are drawn to plants that express cellulase because they are transformed with a nucleic acid encoding endo-β-1,4-glucanase.

Bennett et al disclose a nucleic acid encoding a tomato endo-β-1,4-glucanase and plants

transformed with antisense constructs comprising that nucleic acid expressed behind the chemically inducible E8 promoter and the constitutive CaMV 35S promoter (column 17, line 9, to column, 21, line 49). The tomato endo-β-1,4-glucanse would be "thermostable", and the glucanase has a signal peptide (claims 1-2). Bennett et al do not disclose plants transformed with the construct in a sense orientation.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of transforming plants with an antisense endo-β-1,4-glucanase-encoding construct as taught by Bennett et al, to express the endo-β-1,4-glucanase-encoding in a sense orientation. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Bennett et al to do so (column 3, lines 23-25).

Applicant urges that Lashbrook et al states that endo-β-1,4-glucanase (EC 3.2.1.4) is not a cellulase; thus, '064 does not teach all of the elements of the claims (response pg 7-8).

This is not found persuasive because the enzyme nomenclature database maintained by Swissprot (http://kr.expasy.org/enzyme, 2004) defines a cellulase only as β-1,4-endoglucanases (EC 3.2.1.4) (http://kr.expasy.org/cgi-bin/enzyme-search-de, 2004), which are also known as . Furthermore, the *T. fusca* E1, E2 or E5 enzymes described in the specification are all β-1,4-endoglucanses.

Applicant urges that whether the specification teaches that β-1,4-endoglucanases are cellulases not at issue, only whether Lashbrook teaches or suggest the claimed invention (response pg 8).

This is not found persuasive. The rejection is over Bennett et al, not Lashbrook et al.

Bennett et al states that their enzyme is a β-1,4-endoglucanase, and indicates that any β-1,4-endoglucanase can be used (column 3, lines 23-25). As the enzyme taught by Bennett et al belongs to Enzyme Classification 3.2.1.4, it is a β-1,4-endoglucanase.

11. Claims 6-8, 12-19, 21-23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (1992, US Patent 5,168,064) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407).

The claims are drawn to plants that express cellulase because they are transformed with a nucleic acid encoding endo-β-1,4-glucanase from *T. fusca*.

The teachings of Bennett et al are discussed above. Bennett et al do not disclose nucleic acids encoding endo-β-1,4-glucanase from *T. fusca*.

Lao et al teach nucleic acids encoding the *T. fusca* E2 and E5 endo-β-1,4-glucanases, which are thermostable.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plants transformed with a nucleic acid encoding endo-β-1,4-glucanase as taught by Bennett et al, to use the nucleic acids encoding endo-β-1,4-glucanase from *T. fusca* described in Lao et al. One of ordinary skill in the art would have been motivated to do so because substitution of one endo-β-1,4-glucanase for another would be an obvious optimization of experimental parameters.

12. Claim 9 is free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising a cellulase coding sequence operably linked to a PR-1,

PR-1a, PR-2, PR-3, PR-4, or PR-5 promoter. Claim 20 is free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising nucleic acid encoding a cellulase coding sequence operably linked to vacuole-targeting sequence.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
June 25, 2004

ANNE KUBELIK
PATENT EXAMINER